

REMARKS

Claims 1-6, 8, 9 and 11-24 remain under active prosecution in the present application. Applicants respectfully assert that all amendments are supported by the original disclosure and do not introduce new matter. Moreover, Applicants respectfully assert that the amendments merely clarify and do not further limit or narrow the scope of the claims.

In the subject Office Action dated May 8, 2006:

Claim 6 stands objected to because of potential lack of antecedent basis for the terms "introducer tube" and "introduction assembly". Applicant has made appropriate amendment to correct this informality.

The Examiner has advised that should claims 6 and 9 be found allowable, claims 7 and 10, respectively, will be objected to under 37 CFR 1.75 as being a substantial duplicates thereof. In response, Applicant has canceled Claims 7 and 10.

The Examiner has rejected Claims 1, 3 and 8, 9 and 11 under 35 U.S.C. 102(b) as being anticipated by Barsch (U.S. Patent No. 6,234,177).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the claim. In addition, the elements in the prior art reference must be arranged as required by the claim. MPEP § 2131.

Original Claim 1 claims a method of deployment of a biopsy marker comprising retracting a cutter to expose a cutter lumen of a biopsy probe; inserting a marker and pusher into the cutter lumen; and distally advancing the cutter to drive the pusher and thus the marker to cause deployment at the biopsy surgical site. The Examiner has stated that the cutter and pusher of original Claim 1 do not appear to be patentably distinguishable from the pusher 52 of Barsch; that both elements (cutter and pusher) appear to constitute a single element that is detachably connected together and performs a single function. However, Barsch '177 does not anywhere disclose the step of advancing a cutter to drive plunger 52. Therefore, Applicant respectfully

differs on this point. Nevertheless, Applicant has amended Claim 1 to clarify that the cutter and pusher employed in the claimed method are two separate elements used in steps in the claimed method. Applicant submits that Barsch ('177) fails to teach or suggest all of the limitations recited in amended Claim 1. Barsch ('177) does not teach or suggest use of a pusher having a seat portion configured to abut with a cutter. Barsch ('177) does not teach or suggest bringing a cutter of a biopsy device into abutment with a seat portion of a pusher, or advancing a cutter to drive a pusher to deploy a marker. Accordingly, Barsch ('177) does not anticipate amended Claim 1 in accordance with MPEP § 2131. Applicant, therefore, respectfully requests that the rejection be withdrawn. With respect to Claims 3, 8, 9 and 11, these claims are dependent from Claim 1 and contain all of the limitations thereof, and therefore, are not anticipated by Barsch ('177), for the same reasons.

The Examiner has rejected Claims 2 and 6 under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view Burbank et al. (U.S. Patent No. 6,161,034).

In order for a *prima facie* case of obviousness of a claim to exist, the prior art reference or combination of references must teach or suggest all of the limitations of the claim. MPEP § 2143.03. Additionally, there must be some teaching, suggestion, or motivation to modify the references either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art, in order for a *prima facie* case of obviousness to exist. MPEP § 2143.01. The mere fact that references *can* be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. MPEP § 2143.01. Actual evidence of a suggestion, teaching or motivation to combine prior art references must be shown. *In re Dembiczaik*, 50 USPQ2d 1614 (Fed.Cir. 1999). Broad conclusory statements, standing alone, simply are not evidence. *Id.* Motivation to combine or modify will be lacking if the art teaches away from a claimed combination. MPEP § 2145.

For at least the reasons set forth below, Applicant respectfully submits that the combined art of record fails to render present Claims 2 and 6 obvious. Respectfully differing with the Examiner's conclusion of obviousness, Applicant has, nevertheless, amended independent Claim

1, from which Claims 2 and 6 depend. Applicant submits that the art of record fails to teach or suggest all of the limitations recited in independent Claim 1 in accordance with MPEP § 2143.03. Neither Barsch ('177) nor Burbank et al. ('034), alone or in combination, teach or suggest use of a pusher having a seat portion configured to abut with a cutter. Neither Barsch ('177) nor Burbank et al. ('034) teaches or suggests bringing a cutter of a biopsy device into abutment with a seat portion of a pusher, or advancing a cutter to drive a pusher to deploy a marker. These limitations, among others recited in Claim 1, are neither taught nor suggested by the combined art of record. Applicant, therefore, submits that the combined art of record fails to teach or suggest all of the limitations of Claim 1 in accordance with MPEP § 2143.03. Accordingly, Applicant respectfully submits that the combined art of record fails to render present Claims 2 and 6 (which are dependent from Claim 1) obvious in accordance with MPEP § 2143, and respectfully requests that the rejection be withdrawn.

Even if all of the references in combination did teach or suggest all of the limitations recited in the claims, the Examiner has not identified evidence of a suggestion or motivation to modify or combine the teachings of the references as required by MPEP § 2143. MPEP § 2143.01 admonishes that “[t]he mere fact that references *can* be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.” (Emphasis in original.) Actual evidence of a suggestion, teaching or motivation to combine prior art references must be shown. *In re Dembiczak*, 50 USPQ2d 1614 (Fed.Cir. 1999). Conclusory statements regarding the teaching of references, standing alone, simply are not evidence. *Id.* Thus, the requirements of MPEP § 2143.01 for a *prima facie* case of obviousness are not met. See *In re Dembiczak*, 50 USPQ2d 1614 (Fed.Cir. 1999). The Examiner has not provided the requisite evidence in the prior art suggesting the desirability of the combinations claimed herein. Because evidence of a motivation to combine references required by MPEP § 2143.01 is lacking, Applicant respectfully requests that the rejections be withdrawn.

Claims 4 and 5 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view Zarins et al. (U.S. Patent No. 6,605,047).

As noted above, Applicant has amended independent Claim 1, from which Claims 4 and 5 depend (through dependency on Claim 3). Applicant submits that the art of record fails to teach or suggest all of the limitations recited in independent Claim 1 in accordance with MPEP § 2143.03. Neither Barsch ('177) nor Zarins et al. ('047), alone or in combination, teach or suggest use of a pusher having a seat portion configured to abut with a cutter. Neither Barsch ('177) nor Zarins et al. ('047), alone or in combination, teach or suggest bringing a cutter of a biopsy device into abutment with a seat portion of a pusher, or advancing a cutter to drive a pusher to deploy a marker. These limitations, among others recited in Claim 1, are neither taught nor suggested by the combined art of record. Applicant, therefore, submits that the combined art of record fails to teach or suggest all of the limitations of Claim 1 in accordance with MPEP § 2143.03. Accordingly, Applicant respectfully submits that the combined art of record fails to render present Claims 4 and 5 (which are dependent from Claim 1 through dependency on Claim 3) obvious in accordance with MPEP § 2143, and respectfully requests that the rejection be withdrawn.

The Examiner has rejected Claims 12-15 and 17-19 under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view Burbank et al. (U.S. Patent No. 6,662,041).

Respectfully differing with the Examiner's conclusion that Barsch ('177) and Burbank et al. ('041), alone or in combination, teach or suggest all the elements of Claim 12 as originally submitted, Applicant has, nevertheless, amended independent Claim 12 to further clarify the scope of the claim. Applicant submits that the art of record fails to teach or suggest all of the limitations recited in amended independent Claim 12 in accordance with MPEP § 2143.03. Neither Barsch ('177) nor Burbank et al. ('041), alone or in combination, teach or suggest a pusher having a proximal extension configured for abutment with a cutter to deploy a marker through a lateral distal opening of a tube. Neither Barsch ('177) nor Burbank et al. ('041), alone or in combination, teach or suggest a device for deploying a biopsy marker, having a tube having a tube lateral distal opening configured such that when the tube is inserted into a cutter lumen of a biopsy probe having a probe lateral distal opening, the tube lateral distal opening and the probe lateral distal opening can be aligned at least in part. Neither Barsch ('177) nor Burbank et al.

('041), alone or in combination, teach or suggest a device for deploying a biopsy marker having a tube, a marker and a pusher having a length adapted for cooperation with a cutter of a biopsy instrument such that when the tube, marker and pusher are inserted into a cutter lumen of a biopsy probe, distally advancing the cutter will drive the pusher and cause the marker to be urged through the tube lateral distal opening and the probe lateral distal opening. These limitations, among others recited in amended independent Claim 12, are neither taught nor suggested by the combined art of record. Applicant, therefore, respectfully submits that the combined art of record fails to teach or suggest all of the limitations of Claim 12 in accordance with MPEP § 2143.03. Accordingly, Applicant respectfully submits that the combined art of record fails to render present Claim 12 obvious in accordance with MPEP § 2143, and respectfully requests that the rejection be withdrawn. For the same reasons, Applicant respectfully submits that the combined art of record fails to teach or suggest all of the limitations of Claims 13-15 and 17-19, since these claims are dependent from Claim 12, and requests that the rejection be withdrawn.

Claim 16 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view of Burbank et al. ('041) further in view of Lamoureux et al. (U.S. Patent No. 6,554,760).

Claim 16 also is dependent from Claim 12, through dependency on dependent Claim 13. As discussed immediately above with respect to Claim 12, the limitations recited in Claim 12 are neither taught nor suggested by the combination of Barsch ('177) and Burbank et al. ('041). Lamoureux et al. ('760) also does not teach or suggest these limitations. Further, Lamoureux et al. ('760) does not teach or suggest a removable sealing tip as required by Claim 16. Rather, the "end plug" 32 disclosed by Lamoureux et al. ('760) is not a removable tip, but rather, a biocompatible plug "as a cork in a bottle" (col. 4, l. 9) intended *not* to be removed until it is forced out *within the patient's body* after the needle is inserted. See col. 4, l. 22-33 ("[w]hen the insertion is to the desired depth, the stylet 22 is held firmly and the cannula is drawn back . . . causing the end plug 32 to give way . . . and deposit in the tissue") Applicant, therefore, respectfully submits that the combined art of record fails to teach or suggest all of the limitations of amended independent Claim 12 and dependent Claim 16 in accordance with MPEP § 2143.03.

Accordingly, Applicant respectfully submits that the combined art of record fails to render present Claim 16 obvious in accordance with MPEP § 2143, and respectfully requests that the rejection be withdrawn.

Even if all of the references in combination teach or suggest all of the limitations recited in Claims 12 and 16, the Examiner has not identified evidence of a suggestion or motivation to modify or combine the teachings of the references as required by MPEP § 2143. MPEP § 2143.01 admonishes that “[t]he mere fact that references *can* be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.” (Emphasis in original.) Actual evidence of a suggestion, teaching or motivation to combine prior art references must be shown. *In re Dembiczaak*, 50 USPQ2d 1614 (Fed.Cir. 1999). Conclusory statements regarding the teaching of references, standing alone, simply are not evidence. *Id.* Thus, the requirements of MPEP § 2143.01 for a *prima facie* case of obviousness are not met. See *In re Dembiczaak*, 50 USPQ2d 1614 (Fed.Cir. 1999). Nothing in the cited references teaches or suggests combining the “end plug” 32 of Lamoureux et al. ('760) with the teachings of Barsch ('177) combined with Burbank et al. ('041) to achieve the invention claimed in Claim 16. Based on the reasons discussed above, and in addition, because evidence of a motivation to combine references required by MPEP § 2143.01 is lacking, Applicant respectfully requests that the rejections be withdrawn.

The Examiner has rejected Claims 20-21 and 24 under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view of Miller et al. (U.S. Patent No. 6,638,235).

Respectfully differing with the Examiner's conclusion that Barsch ('177) and Miller et al. ('235), alone or in combination, teach or suggest all the elements of Claim 20 as originally submitted, Applicant has, nevertheless, amended Claim 20 to further clarify the scope of the claimed invention. Applicant submits that the art of record fails to teach or suggest all of the limitations recited in amended independent Claim 20 in accordance with MPEP § 2143.03. Neither Barsch ('177) nor Miller et al. ('235), alone or in combination, teach or suggest a pusher having a proximal extension configured for abutment with a cutter to deploy a marker through a lateral distal opening of a tube. Neither Barsch ('177) nor Miller et al. ('235), alone or in

combination, teach or suggest a system having a tube having a tube lateral distal opening configured such that when the tube is inserted into a cutter lumen of a biopsy probe having a probe lateral distal opening, the tube lateral distal opening and the probe lateral distal opening can be aligned at least in part. Neither Barsch ('177) nor Miller et al. ('235), alone or in combination, teach or suggest a system having a tube, a marker and a pusher having a length adapted for cooperation with a cutter of a biopsy instrument such that when the tube, marker and pusher are inserted into a cutter lumen of a biopsy probe, distally advancing the cutter will drive the pusher and cause the marker to be urged through the tube lateral distal opening and the probe lateral distal opening. These limitations, among others recited in Claim 20, are neither taught nor suggested by the combined art of record. Applicant, therefore, submits that the combined art of record fails to teach or suggest all of the limitations of Claim 20 in accordance with MPEP § 2143.03. Accordingly, Applicant respectfully submits that the combined art of record fails to render present Claim 20 obvious in accordance with MPEP § 2143, and respectfully requests that the rejection be withdrawn. For the same reasons, Applicant respectfully submits that the combined art of record fails to teach or suggest all of the limitations of Claims 21 and 24, since these claims are dependent from amended Claim 20, and requests that the rejection be withdrawn.

The Examiner has rejected Claims 22 and 23 under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view of Miller et al. et al. ('235) further in view of Zarins et al. ('047).

Respectfully differing with the Examiner's conclusion that Barsch ('177), Miller et al. ('235), or Zarins et al. ('047), alone or in combination, teach or suggest all the elements of Claim 20 as originally submitted (from which Claims 23 and 23 depend through dependence on Claim 21), Applicant has, nevertheless, amended Claim 20 to further clarify the scope of the claimed invention. Applicant submits that the art of record fails to teach or suggest all of the limitations recited in amended independent Claim 20 in accordance with MPEP § 2143.03. Neither Barsch ('177), Miller et al. ('235), nor Zarins et al. ('047), alone or in combination, teach or suggest a pusher having a proximal extension configured for abutment with a cutter to deploy a marker through a lateral distal opening of a tube. Neither Barsch ('177), Miller et al. ('235),

nor Zarins et al. ('047), alone or in combination, teach or suggest a system having a tube having a tube lateral distal opening configured such that when the tube is inserted into a cutter lumen of a biopsy probe having a probe lateral distal opening, the tube lateral distal opening and the probe lateral distal opening can be aligned at least in part. Neither Barsch ('177), Miller et al. ('235), nor Zarins et al. ('047), alone or in combination, teach or suggest a system having a tube, a marker and a pusher having a length adapted for cooperation with a cutter of a biopsy instrument such that when the tube, marker and pusher are inserted into a cutter lumen of a biopsy probe, distally advancing the cutter will drive the pusher and cause the marker to be urged through the tube lateral distal opening and the probe lateral distal opening. These limitations, among others recited in Claim 20, are neither taught nor suggested by the combined art of record. Applicant, therefore, respectfully submits that the combined art of record fails to teach or suggest all of the limitations of amended independent Claim 20 in accordance with MPEP § 2143.03.

Accordingly, Applicant respectfully submits that the combined art of record fails to render present amended independent Claim 20 obvious in accordance with MPEP § 2143, and respectfully requests that the rejection be withdrawn. For the same reasons, the combined art of record fails to teach or suggest all of the limitations of Claims 22 and 23, since these claims are dependent from amended Claim 20, and requests that the rejection be withdrawn.

Applicant further notes that the dependent claims include additional limitations not taught or suggested in the art of record, thus forming independent basis for novelty and non-obviousness.

While several distinctions have been noted over the art of record, Applicant notes that there are several other limitations recited in the present claims which are neither taught nor suggested by the art of record. Applicant expressly reserves all rights and arguments with respect to distinctions not explicitly noted herein. In addition, to the extent that the amendments constitute a narrowing of the claims, such narrowing of the claims should not be construed as an admission as to the merits of the prior rejections. Indeed, Applicant traverses the rejections and preserves all rights and arguments. To the extent that any particular statement or argument by the Office in the pending Office Action has not been explicitly addressed herein, the same should

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not be construed as an acquiescence or admission by the Applicant that such statements or arguments by the Office are accurate or proper.

Conclusion

In light of the amendments and remarks made herein, it is respectfully submitted that the claims currently pending in the present application are in form for allowance. Accordingly, reconsideration of those claims, as amended herein, is earnestly solicited. Applicants encourage the Examiner to contact their representative, David Franklin at (513) 651-6856 or dfranklin@fbtlaw.com.

The claims after amendment number 21 total and 3 independent. Since 24 claims total and 3 independent were originally paid for, no fees are due at this time. However, the Commissioner for Patents is hereby authorized to charge any deficiency or credit any overpayment of fees to Frost Brown Todd LLC Deposit Account No. 06-2226.

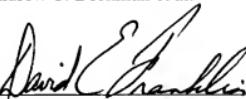
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I hereby certify that a copy of this correspondence is being deposited with the US Patent Office by electronic transmission addressed to MS Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on August 8, 2006.

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